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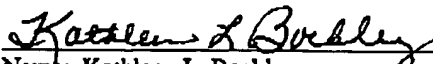
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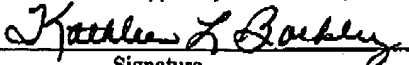
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Jill McFadden et al. Confirmation No.: 2472
Serial No.: 09/097,023 Examiner: M. Hayes
Filing Date: June 12, 1998 Group Art Unit: 3763
Docket No.: 1001.1566101 Customer No.: 28075
For: CATHETER WITH KNIT SECTION

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on March 16, 2005. As indicated on the Fax Cover Letter, Applicants authorize the fee prescribed by 37 C.F.R. § 1.17(c) in the amount of \$500.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Target Therapeutics, Inc., a corporation organized and existing under and by virtue of the laws of Delaware, and having a business address of 47201 Lakeview Boulevard, Fremont, CA 94537. An assignment from the inventors, Jill M. McFadden, Earl Bardsley and Robert Garabedian, conveying all right, title and interest in the invention to Target Therapeutics, Inc. has been recorded at Reel 9458, Frame 0534.

II. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal was previously filed in the present application on March 22, 2002. An Appeal Brief was submitted on May 22, 2002, and thereafter the Examiner withdrew the finality of the rejections in the application and presented new grounds for rejection of the claims. Therefore, the Examiner never submitted a written answer to the Appeal Brief, thus dismissing the appeal from the appeal process.

III. STATUS OF CLAIMS

Claims 16, 23, 43, 49, 57 and 60 have been cancelled from the application. Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by JP 05-220225 in view of Samson, U.S. Patent No. 5,702,373. Samson is relied upon by the Examiner for description of the JP 05-220225 document. Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Leoni, U.S. Patent No. 5,772,681. Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 stand finally rejected under 35

U.S.C. §103(a) as being unpatentable over Cook, U.S. Patent No. 4,637,396, in view of Cox, U.S. Patent No. 5,257,974. Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Cox, and further in view of Leoni. Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni, in view of Andersen et al., U.S. Patent No. 5,674,276. Claims 17, 22, 44 and 48 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni, in view of Jang et al., U.S. Patent No. 4,898,591. Claims 17, 22, 44 and 48 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Cook and Cox, and further in view of Jang et al. Claims 51 and 52 are objected to by the Examiner as being dependent upon a rejected base claim, but the Examiner asserts these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

IV. STATUS OF AMENDMENTS

A Response After Final was filed on January 14, 2005, providing a clean version of all pending claims and accompanying remarks requesting reconsideration in response to a Final Office Action mailed November 16, 2004. An Advisory Action was mailed on February 2, 2005, stating the request for reconsideration was considered, but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER¹

The invention relates to catheters or, more particularly, catheter shaft sections with improved designs. The inventive catheter shaft section includes an elongate tubular member comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member. As illustrated in Figure 4, the knit tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable.

Turning now to the claims, claim 1 recites a catheter section (Figures 2 and 3, reference number 122) comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends. The elongate tubular member comprises a knit tubular member (Figures 2 and 3, reference number 128) and an inner tubular liner (Figure 3, reference number 126) in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops (Figure 4 and Specification, page 8, lines 9-10) and is generally not radially expandable (Specification, page 8, lines 17-20).

Claim 2, which depends from claim 1, further recites that the knit tubular member comprises a metal alloy (Specification, page 7, line 20).

Claim 3, which depends from claim 1, further recites that the knit tubular member comprises a superelastic alloy (Specification, page 7, lines 20-22). Claim 4, which depends from claim 3, recites that the superelastic alloy is a nickel-titanium alloy (Specification, page 7, lines 22-24). Claim 5, which depends from claim 3, recites that the superelastic alloy is nitinol (Specification, page 7, lines 22-24).

¹ The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

Claim 6, which depends from claim 1, further recites that the knit tubular member comprises stainless steel (Specification, page 7, lines 20-22).

Claim 7, which depends from claim 1, further recites that the knit tubular member comprises a platinum alloy (Specification, page 7, lines 20-22).

Claim 8, which depends from claim 1, further recites that the knit tubular member comprises a non-metallic material (Specification, page 7, line 30 through page 8, line 2). Claim 9, which depends from claim 8, recites that the non-metallic material is a polymeric material (Specification, page 7, line 30 through page 8, line 2).

Claim 10, which depends from claim 1, further recites that the knit tubular member comprises a multifilament wire (Specification, page 8, lines 13-15). Claim 11, which depends from claim 10, further recites that the multifilament wire comprises stainless steel and platinum (Specification, page 8, lines 13-16). Claim 12, which depends from claim 10, further recites that the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol (Specification, page 8, line 13-16).

Claim 13, which depends from claim 1, further recites that the knit tubular member is formed from wire having a generally circular cross-sectional shape (Specification, page 8, lines 3-5). Claim 14, which depends from claim 13, further recites that the wire has a diameter of about 0.3 mil—1.5 mil (Specification, page 8, lines 5-6, as amended in an Amendment filed September 26, 2003, of which finds 35 U.S.C. §112, First Paragraph support in claim 14 as originally filed).

Claim 15, which depends from claim 1, further recites that the knit tubular member comprises a first strand made from a first material and a second strand made from a second material (Specification, page 8, lines 11-13).

Claim 54, which depends from claim 1, recites that the catheter section further comprises an outer tubular cover (Figure 3, reference number 130) extending over the knit tubular member. Claim 17, which depends from claim 54, further recites that the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, fluoropolymers including PFTE, FEP, Nylon, polyether block amide, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers (Specification, page 6, line 29 through page 7, line 10). Claim 18, which depends from claim 54, further recites that the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member (Specification, page 6, lines 15-17). Claim 19, which depends from claim 54, further recites that the outer tubular cover is extruded onto the knit tubular member (Specification, page 6, lines 15-17). Claim 20, which depends from claim 54, further recites that the outer tubular cover is bonded onto the knit tubular member (Specification, page 6, lines 15-17). Claim 21, which depends from claim 54, further recites that at least one of the inner tubular liner and the outer tubular cover are radiopaque (Specification, page 7, lines 15-19).

Claim 22, which depends from claim 1, further recites that the inner tubular liner comprises a material selected from the group consisting of polyethylene, fluoropolymer, Nylon, polyether block amide, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyethylene terephthalate (PET), and their mixtures, alloys, and copolymers (Specification, page 6, lines 18-22).

Claim 55, which depends from claim 1, further recites that the knit tubular member is in contact with the inner tubular liner (Figure 3, reference number 126).

Claim 56, which depends from claim 1, further recites that the knit tubular member is formed from a plurality of tightly knit interlocking loops (Specification, page 8, lines 17-20).

Claim 61, which depends from claim 1, further recites that the up loops and down loops are the same size (Specification, page 8, lines 9-10).

Claim 24 is an independent claim directed to a catheter section (Figures 2 and 3, reference number 122) comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends. The elongate tubular member comprises an inner liner (Figure 3, reference number 126), an outer cover (Figure 3, reference number 130), and a knit tubular member (Figures 2 and 3, reference number 128) formed from a metal wire (Specification page 7, line 20) forming a plurality of interlocking up loops and down loops (Figure 4 and Specification, page 8, lines 9-10), wherein the knit tubular member is generally not radially expandable (Specification, page 8, lines 17-20).

Claim 25, which depends from claim 24, further recites that the metal wire comprises a superelastic alloy (Specification, page 7, lines 20-26). Claim 26, which depends from claim 25, further recites that the superelastic alloy is nitinol (Specification, page 7, lines 22-24).

Claim 27, which depends from claim 24, further recites that the metal wire has a generally circular cross-section (Specification, page 8, lines 3-5).

Claim 28, which depends from claim 24, further recites that the metal wire is a multifilament wire (Specification, page 8, lines 13-15). Claim 29, which depends from claim 28, further recites that the multifilament wire comprises stainless steel and platinum (Specification, page 8, lines 13-16). Claim 30, which depends from claim 28, further recites the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol (Specification, page 8, lines 13-16).

Claim 62, which depends from claim 24, further recites that the up loops and down loops are the same size (Specification, page 8, lines 9-10).

Claim 31 is an independent claim directed to a catheter (Figure 1, reference number 100) comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends. The elongate tubular member comprises a relatively stiff proximal segment (Figure 1, reference number 106) and a relatively flexible distal segment (Figure 1, reference number 102 and Figures 2 and 3, reference number 122) comprising a knit tubular member (Figures 2 and 3, reference number 128) and an inner tubular liner (Figure 3, reference number 126) in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops (Figure 4 and Specification, page 8, lines 9-10) and is generally not radially expandable (Specification, page 8, lines 17-20).

Claim 32, which depends from claim 31, further recites that the knit tubular member comprises a superelastic alloy (Specification, page 7, lines 20-22). Claim 33, which depends from claim 32, further recites that the superelastic alloy is nitinol (Specification, page 7, line 22-24).

Claim 34, which depends from claim 31, further recites that the knit tubular member comprises stainless steel (Specification, page 7, lines 20-22).

Claim 35, which depends from claim 31, further recites that the knit tubular member comprises a platinum alloy (Specification, page 7, lines 20-22).

Claim 36, which depends from claim 31, further recites that the knit tubular member comprises a non-metallic material (Specification, page 7, line 30 through page 8, line 2). Claim 37, which depends from claim 36, further recites that the non-metallic material is a polymeric material (Specification, page 7, line 30 through page 8, line 2).

Claim 38, which depends from claim 31, further recites that the knit tubular member comprises a multifilament wire (Specification, page 8, lines 13-15). Claim 39, which depends from claim 38, further recites that the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol (Specification, page 8, lines 13-16).

Claim 40, which depends from claim 31, further recites that the knit tubular member is formed from wire having a generally circular cross-sectional shape (Specification, page 8, lines 3-5). Claim 41, which depends from claim 40, further recites that the wire has a diameter of about 0.3 mil—1.5 mil (Specification, page 8, lines 5-6, as amended in an Amendment filed September 26, 2003, of which finds 35 U.S.C. §112, First Paragraph support in claim 41 as originally filed).

Claim 42, which depends from claim 31, further recites that the knit tubular member comprises a first strand made from a first material and a second strand made from a second material (Specification, page 8, lines 11-13).

Claim 58, which depends from claim 31, recites that the catheter further comprises an outer tubular cover (Figure 3, reference number 130) extending over the knit tubular member. Claim 44, which depends from claim 58, further recites that the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, Nylon, polyether block amide, fluoropolymers including PTFE, FEP, low density polyethylene, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers (Specification, page 6, line 29 through page 7, line 10). Claim 45, which depends from claim 58, further recites that the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member (Specification, page 6, lines 13-17 and page 6, line 29 thru page 7, line 7). Claim 46, which depends from claim 58, further

recites that the outer tubular cover is extruded onto the knit member (Specification, page 6, lines 15-17). Claim 47, which depends from claim 58, further recites that the outer tubular cover is bonded on the knit member (Specification, page 6, lines 15-17). Claim 48, which depends from claim 58, further recites that at least one of the inner tubular liner and the outer tubular cover are radiopaque (Specification, page 7, lines 15-19).

Claim 50, which depends from claim 31, further recites that the proximal segment has an inner proximal liner and an outer proximal cover (Specification, page 10, lines 1-2). Claim 51, which depends from claim 50, recites that the proximal segment further comprises a braid interposed between the inner proximal liner and the outer proximal cover (Specification, page 10, lines 1-12). Claim 52, which depends from claim 50, recites that the proximal segment further comprises a coil interposed between the inner proximal liner and the outer proximal cover (Specification, page 10, lines 1-12).

Claim 53, which depends from claim 31, further recites that the knit tubular member extends into the proximal segment (Specification, page 10, lines 8-9).

Claim 59, which depends from claim 31, further recites that the knit tubular member is formed from a plurality of tightly knit interlocking loops (Specification, page 8, lines 17-20).

Claim 63, which depends from claim 31, further recites that the up loops and the down loops are the same size (Specification, page 8, lines 9-10).

VI. GROUND S OF REJECTION TO BE REVIEWED ON APPEAL

1. *Whether claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 are unpatentable under 35 U.S.C. §102(b) as being anticipated by JP 05-220225, in view of Samson, U.S. Patent No. 5,702,373, relied upon by the Examiner for description of the JP 05-220225 document.*

2. *Whether claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 are unpatentable under 35 U.S.C. §102(e) as being anticipated by Leoni, U.S. Patent No. 5,772,681.*

3. *Whether claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 are unpatentable under 35 U.S.C. §103(a) over Cook, U.S. Patent No. 4,637,396, in view of Cox, U.S. Patent No. 5,257,974.*

4. *Whether claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are unpatentable under 35 U.S.C. §103(a) over Cook, U.S. Patent No. 4,637,396, in view of Cox, U.S. Patent No. 5,257,974, and further in view of Leoni, U.S. Patent No. 5,772,681.*

5. *Whether claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 are unpatentable under 35 U.S.C. §103(a) over JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, in view of Andersen et al., U.S. Patent No. 5,674,276.*

6. *Whether claims 17, 22, 44 and 48 are unpatentable under 35 U.S.C. §103(a) over JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, in view of Jang et al., U.S. Patent No. 4,898,591.*

7. *Whether claims 17, 22, 44 and 48 are unpatentable under 35 U.S.C. §103(a) over Cook, U.S. Patent No. 4,637,396, and Cox, U.S. Patent No. 5,257,974, and further in view of Jang et al., U.S. Patent No. 4,898,591.*

VII. ARGUMENT

A. *Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 are patentable over the §102(b) rejection relying on JP 05-220225 supplemented by the Examiner's reliance of Samson, U.S. Patent No. 5,702,373, for description of the JP 05-220225 document.*

1. *The Examiner improperly relies on the JP 05-220225 document.*

The Examiner suggests JP 05-220225 anticipates the stated rejected claims of the present invention. In upholding the rejection, the Examiner appears to be solely relying on a single paragraph in Samson which briefly characterizes the Japanese document as teaching a "wire layer which is tightly knitted at the proximal section of the catheter and more loosely knitted at a midsection." See Samson, Column 4, Lines 35-41. The Examiner has made a machine-assisted English translation of JP 05-220225 prepared by Thomson Derwent available in the file and accessible on Private PAIR.² Additionally, the Applicants have previously provided a computer translation of JP 05-220225 available from the Japanese Patent Office website (www.jpo.go.jp) with an Amendment mailed May 10, 2004.³ A cursory inspection of these documents shows a disparity of the teachings of the underlying Japanese document. In view of this inconsistency, the Applicants suggest reliance on a machine translation is inappropriate. M.P.E.P. §706.02 states that "[i]f the [prior art] document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection." No certified English translation has been provided as to date, and thus the precise disclosure of the Japanese document has not been established. In *Ex parte Jones*, the Board of Patent Appeals and Interferences expressed its discouragement of the use of foreign language documents in

² A copy is provided in the Documents Appendix.

³ A copy is provided in the Documents Appendix.

rejections and the Examiner's apparent burden of providing translations of such documents when necessary. See *Ex parte Jones*, 62 USPQ2d 1206 (Bd. Pat. App. & Inter. 2001) (unpublished). Therefore, the Examiner's reliance on the JP 05-220225 document as disclosing claimed limitations of the currently claimed invention that the Japanese document does not fairly disclose is without merit.

2. *JP 05-220225 fails to teach or suggest each and every element and structural limitation of the claimed invention.*

"For anticipation under 35 U.S.C. §102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02. Claims 1, 24 and 31 each teach, *inter alia*, a knit tubular member formed from a plurality of interlocking up loops and down loops, wherein the knit tubular member is generally not radially expandable. JP 05-220225 at least fails to teach a knit tubular member, including all the structural limitations, as currently claimed. Therefore, an anticipatory rejection is improper. Although the English language translation of JP 05-220225 uses the term "knitted," it is clear that JP 05-220225 fails to teach a knitted member with all the structural limitations as claimed in the current application. It appears as if the Examiner is relying on JP 05-220225 as teaching a knit member, while disregarding the remainder of the elements claimed in the present invention. For example, the Examiner has failed to identify where JP 05-220225 teaches a knit member formed from a plurality of interlocking up loops and down loops or a knit member generally not radially expandable.

Independent claims 1, 24 and 31 recite a knit tubular member formed from a plurality of interlocking up and down loops that is generally not radially expandable. JP 05-220225 fails to teach either of these structural limitations of the claimed invention. The figures of JP 05-

220225, especially Figures 5A and 7A, show the wires in a woven or crisscross pattern. The figures clearly do not show interlocking up and down loops, as is recited in the instant claims. The figures in JP 05-220225 show a woven or braided member wherein the wires are wrapped in a helical fashion, whereby there are no interlocking up and down loops present. Thus, when the figures of the Japanese document are viewed in light of the accompanying description, it is clear that the term “knit” as used in the document is a surrogate for meaning that the wire is actually woven or braided. There is no teaching or suggestion in the Japanese document of a knit tubular member formed from a plurality of interlocking up and down loops as is instantly claimed.

Likewise, at no point has the Examiner identified where JP 05-220225 teaches a knit member which is generally not radially expandable. This structural limitation must be taught by the prior art reference in order to anticipate the current claims. Applicants’ request that the Examiner identify the location where the Japanese document teaches this structural limitation has gone unanswered. The Examiner simply asserted in the Final Office Action mailed November 16, 2004, “[t]he dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention.” To the contrary, one of skill in the art, upon reviewing the English translation and figures of the Japanese document, would likely conclude that the reinforcing layer (35) was radially expandable in order to achieve the transition from the area of tightly woven wires (35A) to loosely woven wires (35B). See JP 05-220225, paragraph 18. The Examiner has not indicated what language or which figures in JP 05-220225 is being relied on for a teaching of the knit member not being radially expandable.

3. *The definition given to the term “knitted” as used in the current application is dissimilar to that used in JP 05-220225.*

Although the English translation of JP 05-220225 uses the term “knitted” in describing a

reinforcement layer, a reference must be considered for all that it fairly teaches. The Examiner states that the reference must be read in light of its plain meaning. However, Applicants assert the word "knitted" must be construed in view of the specification and the accompanying drawings and must not be given a definition contrary to that disclosed in the document. The Examiner appears to rely solely on the word "knitted" used in the English translation of JP 05-220225 without further evaluation of the document. The Examiner asserted in the Final Office Action mailed November 16, 2004, "[t]he dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention," while rejecting any reliance on the drawings as "a tortuous exercise that is inconclusive and clearly misleading" since the "sketchy figures...lack the appropriate details to accurately discern the elemental structure." Applicants disagree with the Examiner's reliance on the word "knitted" without construing the term in view of the specification and the accompanying drawings. A reference cannot anticipate a claim "by possessing identically named parts," unless those parts also "have the same structure or otherwise satisfy the claim limitations, and were understood to function in the same way by one skilled in the art." *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed. Cir. 1998). The layer taught in JP 05-220225 and shown in Figures 4-7 does not have the same structure as the knitted member of the currently claimed invention; therefore, the reference fails to anticipate the current claims. The Examiner's sole reliance on the word "knit" and failure to recognize the structural differences shown in the drawings in upholding the rejection are without merit.

The machine translation obtained by the Applicants from the Japanese Patent Office website and provided to the Examiner with a Response dated May 10, 2004, suggests a dissimilar definition of "knitted" than that intended in the present application. In the detailed

description of the translation, the method of manufacturing the catheter is described as including forming the wire layer by turns. See JP 05-220225, paragraphs 19 and 23. This description follows what is shown in the figures, which is a wire net that is woven or braided. Additionally, there is a reference to the different pitches in the tight and loose sections. See JP 05-220225, paragraph 19. It is well known in the art that the term "pitch" is commonly used to denote the angle of the strands in a woven or braided material. Thus, when the figures of JP 05-220225 are viewed in light of the specification, it is clear that the term "knit" is being used in a manner dissimilar to that intended in the present application.

There are at least three plain meanings of "knit," provided in the Merriam-Webster Online Dictionary⁴ (obtainable at www.m-w.com), including (1) to tie together; (2) to link firmly or closely; and (3) to form by interlacing yarn or thread in a series of connected loops with needles. Given the different plain meanings possible for "knit," the skilled artisan would logically turn to the figures in the Japanese document in an attempt to determine which meaning of "knit" was intended by the reference. The figures, especially Figures 5A and 7A, show the wires in a woven or crisscross pattern. The figures in JP 05-220225 clearly do not show interlocking up and down loops, as is recited in the currently claimed invention.

The Examiner appears to be selecting a definition of "knit" that is contrary to the figures in the reference in order to assert the reference teaches the claimed invention. Without using the instant specification for guidance, the skilled artisan would interpret the "knitted" reinforcing layer of JP 05-220225 as a woven or braided pattern, as is clearly shown in the reference's figures. While the English translation of the Japanese document uses the word "knitted," there is no teaching or suggestion in the document that the reinforcing layer is formed from a plurality of interlocking up and down loops, as is recited in the current claims.

⁴ A copy is provided in the Evidence Appendix.

4. *The Examiner's inherency argument is flawed.*

The Examiner's assertions in the Final Office Action mailed November 16, 2004, stating, "the dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention" and "the knitted nature of the member would inherently make the member generally not radially expandable" are without merit. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic." M.P.E.P. §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). As previously asserted, the term "knitted" has multiple definitions. The Merriam-Webster Online Dictionary⁵ (obtainable at www.m-w.com) states "knit" may mean: (1) to tie together; (2) to link firmly or closely; or (3) to form by interlacing yarn or thread in a series of connected loops with needles. The fact that the term "knit" has multiple meanings in view of the Figures of the JP 05-220225 reference, which clearly do not show a member formed from a plurality of interlocking up loops and down loops, rebuts any attempt by the Examiner to claim the limitations are inherently present in the prior art reference. Furthermore, adopting the Examiner's assertion in the Final Office Action mailed November 16, 2004, without conceding the correctness of the statement, that "the figures lack the appropriate details to accurately discern the elemental structure," it is improper for the Examiner to make a definitive assertion that JP 05-220225 discloses a knit member formed from a plurality of interlocking up loops and down loops if "knit" can have multiple definitions and the Examiner fails to construe the term in view of the specification and/or drawings.

⁵ A copy is provided in the Evidence Appendix.

Additionally, a knitted member, such as the knitted middle layer 23 taught in Cook, U.S. Patent No. 4,637,396, may be expandable. Therefore, a knitted member is not necessarily not radially expandable as the Examiner erroneously concludes in asserting the structural limitation is inherent in the prior art. Because these limitations are not necessarily taught by the JP 05-220225 reference, the inherency argument suggested by the Examiner is without merit, and JP 05-220225 fails to teach each and every element of the claimed invention. In light thereof, reversal of the rejection based on JP 05-220225 is requested.

B. *Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 are patentable over the §102(e) rejection relying on Leoni, U.S. Patent No. 5,772,681.*

1. *Leoni fails to teach or suggest each and every element and structural limitation of the claimed invention.*

Leoni teaches a dilation catheter having an expandable balloon section (11). The balloon section (11) has a reinforcement net (2) made of metallic monofilaments extending helically around the longitudinal axis of the balloon section (11) and moveable with respect to each other at the crossover points (5) to allow expansion of the balloon section (11). See Leoni, Abstract. The reinforcement net (2) may be wound, braided or knitted. See Leoni, column 2, lines 58-60.

Although Leoni seems to teach a reinforcing net comprising metallic monofilaments that may be helically wound, braided or knitted, Leoni's teachings must be read in light of the specification. Identically named parts in a prior art reference must have the same structure or otherwise satisfy the claim limitations in order to anticipate. See *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed. Cir. 1998).

As discussed above regarding the teachings of JP 05-220225, the Merriam-Webster

Online Dictionary (obtainable at www.m-w.com) contains multiple definitions for the word "knit." Given the different plain meanings possible for "knit," the skilled artisan would logically turn to the remainder of the specification and accompanying figures in the reference in an attempt to determine which meaning of "knit" was intended by the reference. It is apparent from a close examination of Leoni that the definition of "knitted" relied on in Leoni is dissimilar to that intended in the current application. Leoni teaches a reinforcing net made of metallic monofilaments wherein the contact points of the mesh rows are moveable with respect to each other in the crossover points. See Leoni, column 3, lines 55-60. The limitation that the reinforcing net includes mesh rows extending helically around the longitudinal axis, wherein the mesh rows are moveable with respect to each other in the crossover points is as equally limiting for a knitted reinforcing net as it is for a braided reinforcing net as taught in Leoni. See Leoni, column 6, lines 16-34. Claim 6 of Leoni states in part, "wherein said reinforcement net (2) is a knitted net of metallic monofilaments, mesh rows of said net extending helically around the longitudinal axis of the middle section...wherein said mesh rows are moveable with respect to each other in the crossover points (5) during expansion of the balloon section." Thus, the reinforcement net disclosed in Leoni does not have the same structure or otherwise satisfy the structural claim limitations of the current claims. The crossover points are not points of interlocking loops as currently claimed, but are points wherein the mesh rows are moveable with respect to each other. It follows that the definition of "knit" relied on by Leoni is dissimilar from the definition intended in the current application. Further, the structure of the reinforcing mesh is made of metallic monofilaments extending helically around the longitudinal axis of the balloon section and moveable with respect to each other at the crossover points to allow expansion of the balloon section. Therefore, it is apparent that Leoni fails to teach a knitted

tubular member formed from a plurality of interlocking up loops and down loops that is generally not radially expandable.

2. *The Examiner's inherency argument is flawed.*

The Examiner asserted in the Final Office Action mailed November 16, 2004, that "[t]he up and down loops of the knitted member is inherent in view of the dictionary definition of knitted." As stated above regarding the Examiner's inherency argument with respect to the teachings of JP 05-220225, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). It is clear that the missing descriptive matter (i.e., the interlocking up and down loops of the knitted member) is not necessarily present in the reinforcement mesh described in Leoni. The multiple dictionary definitions for knit as well as the description and accompanying drawings describing the reinforcement net of Leoni demonstrate that not only is the claimed limitation not necessarily present in the reference, but Leoni actually teaches a knit member having a dissimilar structure (i.e., the mesh rows of the knitted net are moveable with respect to each other at the crossover points) from the one currently claimed. Therefore, the inherency argument relied on by the Examiner lacks merit, and Leoni fails to anticipate the claimed invention. In light thereof, reversal of the rejection based on Leoni is requested.

C. *Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, and Cox, U.S. Patent No. 5,257,974.*

1. *A reference used to establish a prima facie case of obviousness must be*

analogous art.

In relying on a reference under 35 U.S.C. §103(a), the reference must either be in the field of the Applicant's invention or be reasonably pertinent to the particular problem in which the inventor is concerned. M.P.E.P. §2141.01(a). "While Patent Office classification of references and the cross-references in the official search notes are some evidence of 'nonanalogy' or 'analogy' respectively, the court has found 'the similarities and differences in structure and function of the inventions to carry far greater weight.'" *In re Ellis*, 476, F.2d 1370, 1372, cited at M.P.E.P. §2141.01(a). Neither the art taught in Cook, nor the art taught in Cox are analogous to that of the currently claimed invention or to one another. Furthermore, the knitted member of the current invention functions much differently from that taught in Cook. The knit member in Cook is designed of elastic filaments to provide expansion and contraction characteristics of the balloon. See Cook, column 3, lines 46-48. However, the knit member of the currently claimed invention provides kink resistance and flexibility to a catheter shaft. See Specification, page 3, lines 18-29. Therefore, the inventions taught by Cook and Cox are nonanalogous to that of the currently claimed invention.

2. *There is no suggestion or motivation to combine the teachings of Cook with the teachings of Cox.*

The three basic criteria necessary to establish a *prima facie* case of obviousness with the cited combination are not met with the cited combination of references. Namely, the cited combination at least lacks any suggestion or motivation to combine the teachings of Cook with the teachings of Cox. See M.P.E.P. §2143.01. The teaching or suggestion to make the claimed combination must be found in the prior art, and not in the Applicant's own disclosure. See M.P.E.P. §2143.

i. *The references teach away from one another.*

In ascertaining the differences between the prior art and the currently claimed invention, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. §2141.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) (emphasis in original). The teachings of Cook and Cox actually teach away from one another. Cox teaches an adapter for use with balloons of intravascular balloon catheters. The adapter of Cox may include a support structure comprising reinforcing fibers woven in the shape of a tube. See Cox, column 8, lines 31-34. Cook teaches that an expandable balloon having a knitted layer is superior to prior known fabric reinforced balloons because,

Prior known balloons reinforced with a braided or woven fabric tube are unable to expand in diameter without correspondingly decreasing in length. However, a balloon reinforced with the knitted fabric tube described herein is capable of expanding three-dimensionally such that an increase in diameter does not require a decrease in length of the balloon.

Cook, column 3, lines 48-55 (emphasis added). Therefore, Cook actually teaches away from the teachings of Cox. The language of Cook cited above would discourage one from substituting a woven or braided member for the knitted member of Cook. Additionally, Cox teaches adding a support structure to enhance the radial rigidity of the adapter. However, the knitted layer of Cook is capable of expanding three-dimensionally; therefore, such a knitted layer taught in Cook would not provide the desired radial rigidity which the added support structure of Cox is intended to provide. Therefore, in view of the express teachings of the references, there is no motivation or suggestion to combine the teachings of Cook with those of Cox, and the references actually teach away from one another. Thus, no *prima facie* case of obviousness has been established with the cited combination.

ii. *Modification of one reference with the teachings of the other reference would render the modified apparatus unsatisfactory for its intended purpose.*

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation for combining the teachings of the references found in the prior art. M.P.E.P. §706.02(j). "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. §2143.01, quoting *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). It is apparent that any modification of Cox or Cook with the teachings of the other would make the modified prior art invention unsatisfactory for its intended purpose; therefore, there is no motivation or suggestion to combine the teachings of Cook with the teachings of Cox required to establish *prima facie* obviousness.

Cook teaches a balloon catheter having a balloon reinforced by a knitted layer comprising elastic and inelastic plies. See Cook, column 3, lines 10-15. The knitted middle layer (23), as shown in Figure 2, is an interior layer of the balloon positioned between the inner layer (22) and the outer layer (24). By using elastic plies, the knitted layer is expandable, and the knitted layer is chosen for its expansion and contraction characteristics. See Cook, column 3, lines 45-48. Therefore, the expandable knitted layer imbedded in the balloon allows the balloon to expand to a predetermined diameter.

Cox, on the other hand, teaches an adapter for use with balloons of intravascular balloon catheters. The adapter, which may be placed about the exterior of the balloon, is preferably made of a material providing radial rigidity to the adapter, and serves to restrict the balloon's radial size. See Cox, column 5, lines 41-44. The adapter of Cox may include a support structure comprising reinforcing fibers woven in the shape of a tube. See Cox, column 8, lines 31-34.

The woven support structure is included in order to enhance the radial rigidity of the adapter. See Cox, column 8, lines 44-45. It is clear that any support structure added to the adapter of Cox is intended to provide enhanced rigidity to the adapter to reduce radial expansion.

Modifying the Cook reference with the woven support structure suggested in Cox would impart undesired rigidity into the balloon of Cook and prevent desired expansion of the balloon, therefore making the modified invention unsatisfactory for its intended purpose. Likewise, modifying Cox with the expandable knitted member taught in Cook would impart undesired expansion to the adapter taught in Cox. The expandable knitted member would not aid in enhancing the radial rigidity of the adapter; therefore, the proposed modification would not improve the performance of the adapter taught in Cox. Because such a proposed modification of either reference would render the prior art invention unsatisfactory for its intended purpose, there is no motivation to combine the teachings of Cox and Cook. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

D. *Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, Cox, U.S. Patent No. 5,257,974, and Leoni, U.S. Patent No. 5,772,681.*

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the remarks provided above concerning each of the references are equally applicable to the instantly cited combination. The references at least fail to teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable.

Additionally, there is no motivation to combine the teachings of the combination of references in order to reach the invention as claimed in the rejected claims. As stated above, there is no motivation or suggestion to combine the teachings of Cook with those of Cox. The references actually teach away from one another and modification of one in view of the other would make the modified device unsatisfactory for its intended purpose. Leoni fails to provide motivation to combine the references lacking in Cook and Cox. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

E. *Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, and Andersen et al., U.S. Patent No. 5,674,276.*

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the cited combination at least fails to teach each and every element of the claimed invention. As explained above, neither JP 05-220225 nor Leoni teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable. Andersen et al., relied on by the Examiner to teach using multifilaments with first and second materials of a metal and a polymer, fail to remedy the shortcomings of JP 05-220225 and Leoni. Andersen et al. teach a tubular stent graft formed of loosely interlocked knitted loops. See Andersen et al., column 4, lines 25-27. However, the tubular stent graft is self-expanding or otherwise readily expandable. See Andersen, column 3, lines 18-20. Therefore, Andersen et al. at least fail to teach a knitted member that is generally not radially expandable.

Additionally, there is no motivation to combine the teachings of Andersen et al. with those of either JP 05-220225 or Leoni. The stent graft taught in Andersen et al. is nonanalogous to the catheter shaft taught in either JP 05-220225 or the dilation balloon taught in Leoni. Furthermore, the nature of the problem to be solved in Andersen et al. is dissimilar to that of either JP 05-220225 or Leoni. One of skill in the art would not be inclined to look to an expandable stent graft as taught in Andersen et al. in an attempt to modify the device taught in either JP 05-220225 or Leoni. There is no motivation, either expressly or impliedly, to make the suggested combination. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

F. *Claims 17, 22, 44 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, and Jang et al., U.S. Patent No. 4,898,591.*

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the cited combination at least fails to teach each and every element of the claimed invention. As explained above, neither JP 05-220225 nor Leoni teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable. Jang et al., relied on by the Examiner to teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, fail to remedy the shortcomings of JP 05-220225 and Leoni. Jang et al. suggest a braided body portion, but fail to teach a knitted tubular member including all relevant structural limitations as currently claimed. As stated above, the dissimilar characteristics of a braided member and a knitted member as

currently claimed are not insignificant. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

G. Claims 17, 22, 44 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, Cox, U.S. Patent No. 5,257,974, and Jang et al., U.S. Patent No. 4,898,591.

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the cited combination at least fails to teach each and every element of the claimed invention. As explained above, neither Cook nor Cox individually or in combination teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable. Jang et al., relied on by the Examiner to teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, fail to remedy the shortcomings of Cook and Cox. Jang et al. suggest a braided body portion, but fail to teach a knitted tubular member including all relevant structural limitations as currently claimed. As stated above, the dissimilar characteristics of a braided member and a knitted member as currently claimed are not insignificant.

Additionally, as stated above, there is no motivation to combine the teachings of Cook with those of Cox. The references actually teach away from one another and modification of one in view of the other would make the modified device unsatisfactory for its intended purpose. Jang et al. fail to remedy the shortcomings of Cook and Cox and provide motivation to combine the teachings of the cited combination. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the

combination is requested.

H. Conclusion.

For the reasons stated above, the rejection of claims 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 under 35 U.S.C. §§102(b), 102(e) and 103(a) should be reversed.


Respectfully submitted,

Jill McFadden, et al.

By their attorney,

Date: _____

5/16/05



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VIII. CLAIMS APPENDIX

1. A catheter section comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends, said elongate tubular member comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable.

2. The catheter section of claim 1 wherein the knit tubular member comprises a metal alloy.

3. The catheter section of claim 1 wherein the knit tubular member comprises a superelastic alloy.

4. The catheter section of claim 3 wherein the superelastic alloy is a nickel-titanium alloy.

5. The catheter section of claim 3 wherein the superelastic alloy is nitinol.

6. The catheter section of claim 1 wherein the knit tubular member comprises stainless steel.

7. The catheter section of claim 1 wherein the knit tubular member comprises a platinum alloy.

8. The catheter section of claim 1 wherein the knit tubular member comprises a non-metallic material.

9. The catheter section of claim 8 wherein the non-metallic material is a polymeric material.

10. The catheter section of claim 1 wherein the knit tubular member comprises a multifilament wire.

11. The catheter section of claim 10 wherein the multifilament wire comprises stainless steel and platinum.

12. The catheter section of claim 10 wherein the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol.

13. The catheter section of claim 1 wherein the knit tubular member is formed from wire having a generally circular cross-sectional shape.

14. The catheter section of claim 13 wherein the wire has a diameter of about 0.3 mil – 1.5 mil.

15. The catheter section of claim 1 wherein the knit tubular member comprises a first strand made from a first material and a second strand made from a second material.

17. The catheter section of claim 54 wherein the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, fluoropolymers including PTFE, FEP, Nylon, polyether block amide, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers.

18. The catheter section of claim 54 wherein the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member.

19. The catheter section of claim 54 wherein the outer tubular cover is extruded onto the knit tubular member.

20. The catheter section of claim 54 wherein the outer tubular cover is bonded onto the knit tubular member.

21. The catheter section of claim 54 wherein at least one of the inner tubular liner and the outer tubular cover are radiopaque.

22. The catheter section of claim 1 wherein the inner tubular liner comprises a material selected from the group consisting of polyethylene, fluoropolymer, Nylon, polyether block amide, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyethylene terephthalate (PET), and their mixtures, alloys, and copolymers.

24. A catheter section comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends, said elongate tubular member comprising an inner liner, an outer cover, and a knit tubular member formed from a metal wire forming a plurality of interlocking up loops and down loops, wherein the knit tubular member is generally not radially expandable.

25. The catheter section of claim 24 wherein the metal wire comprises a superelastic alloy.

26. The catheter section of claim 25 wherein the superelastic alloy is nitinol.

27. The catheter section of claim 24 wherein the metal wire has a generally circular cross-section.

28. The catheter section of claim 24 wherein the metal wire is a multifilament wire.

29. The catheter section of claim 28 wherein the multifilament wire comprises stainless steel and platinum.

30. The catheter section of claim 28 wherein the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol.

31. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:

a relatively stiff proximal segment; and

a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable.

32. The catheter of claim 31 wherein the knit tubular member comprises a superelastic alloy.

33. The catheter of claim 32 wherein the superelastic alloy is nitinol.

34. The catheter of claim 31 wherein the knit tubular member comprises stainless steel.

35. The catheter of claim 31 wherein the knit tubular member comprises a platinum alloy.

36. The catheter of claim 31 wherein the knit tubular member comprises a non-metallic material.

37. The catheter of claim 36 wherein the non-metallic material is a polymeric material.

38. The catheter of claim 31 wherein the knit tubular member comprises a multifilament wire.

39. The catheter of claim 38 wherein the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol.

40. The catheter of claim 31 wherein the knit tubular member is formed from wire having a generally circular cross-sectional shape.

41. The catheter of claim 40 wherein the wire has a diameter of about 0.3 mil. – 1.5 mil.

42. The catheter of claim 31 wherein the knit tubular member comprises a first strand made from a first material and a second strand made from a second material.

44. The catheter of claim 58 wherein the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, Nylon, polyether block amide, fluoropolymers including PTFE, FEP, low density polyethylene, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers.

45. The catheter of claim 58 wherein the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member.

46. The catheter of claim 58 wherein the outer tubular cover is extruded onto the knit member.

47. The catheter of claim 58 wherein the outer tubular cover is bonded on the knit member.

48. The catheter of claim 58 wherein at least one of the inner tubular liner and the outer tubular cover are radiopaque.

50. The catheter of claim 31 wherein the proximal segment has an inner proximal liner and an outer proximal cover.

51. The catheter of claim 50 wherein the proximal segment further comprises a braid interposed between the inner proximal liner and the outer proximal cover.

52. The catheter of claim 50 wherein the proximal segment further comprises a coil interposed between the inner proximal liner and the outer proximal cover.

53. The catheter of claim 31 wherein the knit tubular member extends into the proximal segment.

54. The catheter of claim 1 further comprising an outer tubular cover extending over the knit tubular member.

55. The catheter of claim 1 wherein the knit tubular member is in contact with the inner tubular liner.

56. The catheter of claim 1 wherein the knit tubular member is formed from a plurality of tightly knit interlocking loops.

58. The catheter of claim 31 further comprising an outer tubular cover extending over the knit tubular member.

59. The catheter of claim 31 wherein the knit tubular member is formed from a plurality of tightly knit interlocking loops.

61. The catheter of claim 1 wherein the up loops and down loops are the same size.

62. The catheter of claim 24 wherein the up loops and down loops are the same size.

63. The catheter of claim 31 wherein the up loops and down loops are the same size.

IX. EVIDENCE APPENDIX

A. Merriam-Webster Online Dictionary (www.m-w.com) submitted with Amendment dated May 10, 2004. The Examiner entered the evidence as indicated in the Office Action mailed May 28, 2004 stated at page 2, paragraph 1 "Applicant's submission filed on 5/10/04 has been entered."

B. JP 05-220225 and Machine-assisted English translation of JP 05-220225 prepared by Thomson Derwent and available on Private PAIR. The Examiner entered the untranslated evidence in the Office Action mailed June 27, 2003. The Examiner entered the translated evidence in the Final Office Action mailed November 16, 2004.

C. Computer-assisted English translation of JP 05-220225 available at the Japan Patent Office website (www.jpo.go.jp) and submitted with Amendment dated May 10, 2004. The Examiner entered the evidence as indicated in the Office Action mailed May 28, 2004 stated at page 2, paragraph 1 "Applicant's submission filed on 5/10/04 has been entered."